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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,950	03/20/2002	Frederic J de Sauvage	P1748R1E	4737

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EXAMINER	
HUNNICUTT, RACHEL KAPUST	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,950	DE SAUVAGE ET AL.	
	Examiner	Art Unit	
	Rachel K. Hunnicutt	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-14,19,21,22 and 26-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18,20, and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0702*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VIII (encompassing claims 15-20 and 23-25) is acknowledged. In response to the election of species requirement, Applicants have elected allergic disorders and asthma. The traversal is on the ground(s) that the International Preliminary Examination Report did not find a lack of unity of invention, and the Examiner has not shown that the determination of unity of invention during the International Preliminary Examination was not proper.

Applicant's argument have been fully considered but have not been found to be persuasive. The International Preliminary Examination Report (IPER) is not binding on the examination of applications before the U.S. Patent and Trademark office. Thus, it is possible to find a lack of unity of invention even though it was not found in the IPER. In addition, the Examiner did show that there was a lack of unity of invention (see p. 4 of paper no. 20040519).

The restriction requirement is still deemed proper and is therefore made FINAL. Claims 1-14, 19, 21-22, and 26-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 15-18, 20, and 23-25 are under consideration as they are drawn to methods of administering monoclonal antibodies for the treatment of asthma.

Specification

The use of the trademarks TAQMAN™ (p. 8), TWEEN™ (p. 10), PLURONICS™ (p. 10), MATCHMAKER™ (p. 46), PLEXIGLAS™ (p. 68), SUPERFROST PLUS™ (p. 71), DIFF-QUIK™ (p. 71), SUPERFECT™ (p. 72), FUGENE™ (p. 72), BACULOGOLD™ (p. 74), EX-CELL™ (p. 75), CELLFECTIN™ (p. 75), and SEPHAROSE™ (p. 75) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see, for example, p. 14 and 17). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-18, 20, and 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering anti-TCCR antibodies in order to prevent, inhibit or attenuate the differentiation of T-cells into Th2 cells, does not reasonably provide enablement for administering any antibody and having the effect of preventing, inhibiting or attenuating the differentiation of T-cells into Th2 cells. The specification does not enable any skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention; 2) state of the prior art; 3) relative skill of those in the art; 4) level of predictability in the art; 5) existence of working examples; 6) breadth of claims; 7) amount of direction or guidance by the inventor; and 8) quantity of experimentation needed to make and/or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 15-18, 20, and 23-25 are examined as they are drawn to methods of administering monoclonal antibodies to prevent, inhibit or attenuate the differentiation of T-cells into Th2 cells

and to treat Th2-mediated diseases such as asthma. One skilled in the art would not know how to use any monoclonal antibody such that it would prevent, inhibit or attenuate the differentiation of T-cells into Th2 cells. In order for the method to be effective, it appears that the monoclonal antibody must bind to a cytokine receptor such as TCCR.

Claims 17, 18, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of treating Th2-mediated diseases such as asthma by administering TCCR agonists that are monoclonal antibodies. The effect of the treatment would be stimulating differentiation into Th1 cells while inhibiting differentiation into Th2 cells. Lewis teaches that it is unclear whether enhancing Th1 responses is a desirable goal of immunotherapy, particularly in the case of atopic disorders in which there is established chronic inflammation, such as asthma (2002, *Curr. Opin. Immun.* 14: 644-651, see p. 648). Lewis teaches that recent human trials of altered peptide ligands for the treatment of autoimmune disease indicate that it may be difficult to predict the in vivo consequences of these agents on T cell immunity from in vitro studies. The specification does not provide any examples of administering monoclonal antibodies for the treatment of Th2-mediated diseases such as asthma.

Due to the lack of guidance provided by the specification, the unpredictability of the art, the lack of working examples, the nature of the invention, and the state of the prior art, one skilled in the art would not know how to treat Th2-mediated diseases such as asthma by administering monoclonal antibodies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-18, 20, and 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,323,027. Claims 15 and 16 are drawn to a method of preventing, inhibiting or attenuating the differentiation of T-cells into Th2 cells by administering monoclonal antibodies. Claims 17, 18, 20, and 23-25 are drawn to a method for treating asthma by administering monoclonal antibodies. The '027 patent teaches methods for selectively treating Th2-based disorders such as asthma by administering a gc chain blocking agent (column 35). The preferred gc blocking agent is a monoclonal antibody that specifically binds to an antigenic determinant of the gc chain of cytokine receptors (column 5). The antibodies may be fragments or single-chain antibodies (see column 13). The antibodies may also be humanized (see column 16). The '027 patent teaches methods of inhibiting the differentiation of Th2 cells by administering the gc blocking agents (column 26). Thus, claims 15-18, 20, and 23-25 are anticipated by the '027 patent.

Claims 15-17, 23, and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Mattson *et al.* (International Publication No. WO 99/40195). Claims 15-17 and 23-25 are as stated above. Mattson *et al.* teach monoclonal antibodies that recognize the DNAX Cytokine Receptor Subunit 1 (DCRS1) (see p. 56). Mattson *et al.* teach antibody fragments and single-chain antibodies (p. 56). DCRS1 is 99.8% identical to the TCCR polypeptide. Mattson *et al.* teach administering agonistic anti-DCRS1 monoclonal antibodies for the treatment of immunological disorders (p. 67). Such agonistic anti-DCRS1 monoclonal antibodies would

inherently prevent, inhibit or attenuate the differentiation of T-cells into Th2 cells. Thus, claims 15-17, 23, and 25 are anticipated by Mattson *et al.*

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 15-18, 20, and 23-25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15-18, 20, and 23-25 of copending Application No. 10/663158. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and/or published patent applications are considered pertinent to the instant application:

U.S. Patent No. 5,792,850. The Zcytor1 polypeptide is 100% identical to the TCCR polypeptide sequence. However, the '850 patent teaches administering agonist ligands for stimulating cell-mediated immunity and for stimulating lymphocyte proliferation and administering antagonist ligands for suppressing the immune system.

U.S. Patent Publication No. 2004/0219096. The application teaches administering agonists of IL-27 for the treatment of asthma, but it was filed after the filing date of the current application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
3/21/05

JANET ANDRES
PRIMARY EXAMINER